

# Self-monitoring of blood glucose (SMBG): comparison of no SMBG, SMBG alone and SMBG with telecare

|                                        |                                                                |                                                                                                   |
|----------------------------------------|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>16/04/2014   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>15/05/2014 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>07/10/2020       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

For people with diabetes monitoring the level of glucose in the blood is an important part of managing their condition. Self-monitoring of blood glucose (SMBG) involves a person with diabetes monitoring their own blood glucose levels using a blood glucose meter. SMBG has been widely accepted as essential for people with type 1 and type 2 diabetes who have insulin injections for their diabetes, as the information gained from the monitoring can help decide the insulin dose required and prevent blood glucose levels from going too low. It can also help the person with diabetes adjust their diet and exercise to better control their blood glucose levels. However, for people with diabetes who do not take insulin and manage their diabetes by taking tablets or through diet and exercise alone, there is a continuing debate regarding the benefit of SMBG. People with type 2 diabetes have their blood glucose level measured at least annually by their GP. It is measured in terms of their Haemoglobin A1c level (or HbA1c). If HbA1c levels are too high, various anti-diabetic medications may be prescribed. Previous studies have not shown consistently that there is an improvement in patients HbA1c levels when they have used SMBG compared to those who haven't. However, it has not always been clear how the patients were monitoring, what action they took as a result of their blood glucose readings and what action their health care professional (GP, diabetes doctor, nurse) took. Without either the patient or health care professional taking any action, it has been shown that SMBG alone will not make a difference. This study will therefore look at whether there is a difference in HbA1c levels after 12 months in patients with type 2 diabetes who use SMBG compared to those who do not, when diabetes education and SMBG training is given to patients. Health care professionals will also be encouraged to take action to adjust medication based on the regular blood glucose readings as opposed to the HbA1c results. The study will also look at how much support needs to be given to patients using SMBG by providing some patients with additional monthly advice and support from a study nurse.

### What does the study involve?

People aged between 18 and 80 with type 2 diabetes who are not currently treated with insulin will be invited to take part in the study.

What does the study involve?

Those who take part in the study will be asked to visit their nearest research clinic (this will be their GP practice or local hospital) every 3 months over a 12-month period. They will be randomly allocated to one of three groups. Group 1 will not monitor their blood glucose. Group 2 will monitor their blood glucose (SMBG group). Group 3 will monitor their blood glucose and will also discuss their readings with the study nurse by phone each month and action will be taken where needed (SMBG with telecare group). Participants allocated to the SMBG groups will be asked to attend training so that they can be taught how to use the blood glucose meters. In total, patients in all groups may be asked to attend the clinic up to seven times over the course of the year with each visit lasting between 20 minutes to 1 hour. They will see their GP and other health care professional as normal and will also attend the research clinic every 3 months for some basic clinical measurements to be taken such as HbA1c and cholesterol levels. At the research centre visits they will complete some questionnaires asking about their general well-being and their diabetes.

What are the possible benefits and risks of participating?

Those who take part in the study may benefit from better control of their blood glucose and more appropriate treatment for their diabetes. There are no risks to taking part in the study as patients will be receiving standard care as they should be receiving now. The only difference being that treatment may be more targeted or intensified in patients allocated to the SMBG groups, but this remains to be seen.

Where is the study run from?

15 sites in the UK (see below).

When is the study starting and how long is it expected to run for?

The study started in December 2012 and is expected to run until June 2016.

Who is funding the study?

European Foundation for the Study of Diabetes (EFSD) (Germany).

Who is the main contact?

Sharon Parsons

S.N.Parsons@swansea.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Ms Sharon Parsons

**Contact details**

Singleton Park

Swansea

United Kingdom

SA2 8PP

## Additional identifiers

**Protocol serial number**

12038

## **Study information**

**Scientific Title**

Self-monitoring of blood glucose (SMBG): a randomised controlled trial comparing no SMBG, SMBG alone and SMBG with telecare

**Acronym**

SMBG

**Study objectives**

To determine whether HbA1c is significantly altered at 12 months in patients who receive SMBG compared to the control group.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South East Wales REC panel C, 07/02/2011, 10/WSE03/50

**Primary study design**

Interventional

**Study design**

Randomised; Interventional; Design type: Process of Care

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Topic: Diabetes; Subtopic: Type 2; Disease: Diabetic Control

**Interventions**

Participants will be randomised into one of the following three groups:

Group 1: no self monitoring of blood glucose (SMBG), usual diabetes care, general diabetes education via booklet, research clinic visits every 3 months for 12 months

Group 2: SMBG with self adjustment, usual diabetes care, general diabetes education via booklet, SMBG training using Accu-Chek 360° and pattern recognition, use of patient algorithm for self-management adjustment, agreed goal setting/care plan using SMBG readings\* at research clinic visits every 3 months for 12 months, refresher training on SMBG at each research clinic visit

Group 3: SMBG with telecare, usual diabetes care, general diabetes education via booklet, SMBG training using Accu-Chek 360° and pattern recognition, use of patient algorithm for self-

management adjustment, agreed goal setting/care plan using SMBG readings\* at monthly intervals over the phone and research clinic visits every 3 months for 12 months, refresher training on SMBG at each research clinic visit

\*4-point blood glucose profile to be taken 2 days every week (1 day during the week, 1 day during the weekend). 7-point profile to be taken for 3 days the week before the research clinic visit. Results uploaded to study nurse for review as part of care plan.

Patient follow-up is for 12 months in all patient groups.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

HbA1c result; Timepoint(s): at 12 months

### **Key secondary outcome(s)**

Not provided at time of registration

### **Completion date**

30/09/2016

## **Eligibility**

### **Key inclusion criteria**

1. Type 2 diabetes mellitus patients with a duration of diabetes > 1 year
2. Age 18-80 years
3. HbA1c levels between  $\geq 7.5\%$  and  $\leq 13\%$
4. Willing and able to provide informed consent
5. Access to a telephone
6. Able to make blood glucose measurements

Target Gender: Male & Female; Upper Age Limit 80 years ; Lower Age Limit 18 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Other

### **Lower age limit**

18 Years

### **Upper age limit**

80 Years

**Sex**

All

**Total final enrolment**

446

**Key exclusion criteria**

1. Diabetes other than type 2 diabetes mellitus (e.g., GAD positive) or treated with insulin
2. Pregnancy
3. Gestational diabetes mellitus
4. Severe chronic hepatic disease
5. Need to use SMBG as part of clinical care
6. Participation in any investigational drug trial within 1 month prior to Visit 1
7. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study
8. End-stage renal disease (existing or planned dialysis or transplantation) or creatinine >150 umol/L
9. Blindness or severe loss of visual acuity in both eyes

**Date of first enrolment**

04/12/2012

**Date of final enrolment**

30/06/2015

**Locations****Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

**Joint Clinical Research Facility**

ILS2

Swansea University

Swansea

United Kingdom

SA2 8PP

**Study participating centre**

**Wrexham Maelor Hospital**

Wrexham

United Kingdom

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**Study participating centre**  
**St Thomas & West Cross Surgeries**  
Swansea  
United Kingdom

-

**Study participating centre**  
**Diabetes Centre**  
Glangwili Hospital  
Carmarthen  
United Kingdom

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**Study participating centre**  
**Bellevue Practice**  
Newport  
United Kingdom

-

**Study participating centre**  
**Clinical Research Centre**  
Prince Philip Hospital  
Llanelli  
United Kingdom

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**Study participating centre**  
**Sketty & Killay Surgeries**  
Swansea  
United Kingdom

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**Study participating centre**  
**Withybush Hospital**  
Haverfordwest  
United Kingdom

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**Study participating centre**  
**Castle Surgery**  
Neath  
United Kingdom

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**Study participating centre**  
**Clarence Medical Centre**  
Rhyl  
United Kingdom

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**Study participating centre**  
**The Practice of Health**  
Barry  
United Kingdom

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**Study participating centre**  
**Llandaff North Medical Centre**  
Cardiff  
United Kingdom

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**Study participating centre**  
**Countess of Chester Hospital**  
Chester  
United Kingdom

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**Study participating centre**  
**Oakenhurst Medical Centre**  
Blackburn  
United Kingdom

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**Study participating centre**  
**Ystradgynlais Group Practice**  
Ystradgynlais

United Kingdom

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## Sponsor information

### Organisation

Abertawe Bro Morgannwg University Health Board (UK)

### ROR

<https://ror.org/04zet5t12>

## Funder(s)

### Funder type

Research organisation

### Funder Name

European Foundation for the Study of Diabetes (Germany)

### Alternative Name(s)

The European Association for the Study of Diabetes, European Association for the Study of Diabetes (EASD), EFSD

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Germany

### Funder Name

Roche Diagnostics GmbH (Switzerland)

## Results and Publications

Individual participant data (IPD) sharing plan



The datasets generated during and/or analysed during the current study are available upon request from Dr Sharon Parsons (S.N.Parsons@Swansea.ac.uk) once all analyses and publications have been completed.

## IPD sharing plan summary

Available on request

### Study outputs

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results  | 01/05/2019   | 28/09/2020 | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 26/01/2017   |            | Yes            | No              |